K051985

510(K) Summary
AUG 17 2005

5. Summary of Safety and Effectiveness

Submitted By: Scott Huie
Vice President of Operations
Biovalve Technologies, Inc

Date Prepared: 21 July, 2005

5.1. Trade/Proprietary Name: Biovalve Mini-Ject Needlefree Injection Systems

5.2. Common/Usual Name: Needlefree Injector; Jet Injector

5.3. Classification Name: Non-Electrically Powered Fluid Injector

5.4. Classification:

FDA has classified Non-Electrically Powered Fluid Injector Jet Injectors in Class II. Final Order was published in the Federal Register on October 21, 1980 after review by the General Hospital and Personal Use Devices Classification Panel

Panel: 80 Procode: KZE- Non-Electrically Powered Fluid Injector Jet Injectors

5.5. Purpose of Submission

To update the Instructions for Use for the currently marketed Needlefree Injector in order to clarify and simplify the warnings, precautions and contraindications sections.

5.6. Substantial Equivalence

The product with the modified Instructions for Use is substantially equivalent to the currently marketed product.

5.7. Technological Characteristics

This is a label only modification and as a result it does not change the technological characteristics of the current product.

5.8. Performance Data

No change was made to the Mini-Ject device and therefore no physical testing was required to confirm the injectors meet their specifications.

5.9. Conclusion

BioValve, Inc. concludes based on the information presented that the modified product (i.e. modified Instruction for Use) is substantially equivalent to the current product legally marketed in the USA.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 17 2005

Mr. Scott Huie
Vice President of Operations
BioValve Technologies, Incorporated
155 Flanders Road
Westborough, Massachusetts 01581

Re: K051985
Trade/Device Name: BioValve Mini-Ject Needlefree Injection System
Regulation Number: 21 CFR 880.5430
Regulation Name: Nonelectrically powered fluid injector
Regulatory Class: II
Product Code: KZE
Dated: July 21, 2005
Received: July 25, 2005

Dear Mr. Huie:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number: K051985

Device Name: BIOVALVE MINI-JECT NEEDLEFREE INJECTIO SYSTEM

Indications for Use:

The Mini-Ject device is a needle-free injection system designed to deliver fluid subcutaneously. This nonelectrically powered device is intended to deliver an injection of fluid by means of a high velocity jet of fluid that penetrates the skin and delivers the fluid to the subcutaneous area of the body. The Mini-Ject device is intended for home and professional use. It may be used by physicians, nurses and other practitioners who routinely administer injections and by patient authorized by their physicians to self inject at home.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: ✓ **or** **Over-the-Counter Use:** _____

(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General Hospital,
Infection Control, Dental Devices

510(k) Number K051985